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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,969	04/11/2002	Bang Luu	211815US0	9550
22850	7590	06/01/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.			TRAVERS, RUSSELL S	
1940 DUKE STREET			ART UNIT	PAPER NUMBER
ALEXANDRIA, VA 22314			1617	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/890,969	LUU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Russell Travers, J.D., Ph.D	1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                   |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

The information disclosure statement filed November 19, 2001 has been received and entered into the file.

Claims 1-9 are presented for examination.

Claim 4 provides for the use of cyclohexanone, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 4 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3 and 5-6 are rejected under 35 U.S.C. § 102(a) as being anticipated by *Girlanda-Junges et al* (u) or (v).

Applicant's attention is drawn to *In re Dillon*, 16 USPQ2nd 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-3 and 5-9 are rejected under 35 U.S.C. § 103 as being unpatentable over Borg and Girlanda-Junges et al.

Borg teaches the genus encompassing the instant claimed compounds (see columns 3-4, and claims 1) as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. Girlanda-Junges et al (u) or (v) teach the instant claimed compounds (see page 7736, Scheme 1) as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form (see page 7749). These medicaments are recited respectively as useful for

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treating various neurodegenerative diseases (see column 13, (a) and (c) and (column 1, line 51)), and effective to "alter the pathogenesis of neurodegenerative diseases" (page 7735, paragraph 1), viewed by the skilled artisan as indistinguishable from those uses herein recited.

Claims 7-9, and the primary reference, differ as to:

- 1) exemplification of the claimed medicaments for treating ALS,
- 2) recitation of intended use for the instant compositions, and
- 3) failure to recite the mechanism by which Applicants postulate therapy is mediated

Examiner again notes Borg teaches the compound genus encompassing the instant claimed compounds (see columns 3-4, and claim 1) as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. Girlanda-Junges et al (u) or (v) teach the instant claimed compounds (see page 7736, Scheme 1) as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form (see page 7749). Possessing the Borg teaching the skilled artisan would possess all those compounds set forth in columns 3-4 and claim 1, for the neuro-therapeutic use herein recited. Attention is directed to Borg teaching the genus of compounds encompassing those envisioned by Applicants as useful for treating various neurodegenerative diseases (see column 13, (a) and (c) and (column 1, line 51)), thereby motivating the skilled artisan to employ these compounds for treating ALS (amyotrophic lateral sclerosis) and enjoy a reasonable expectation of therapeutic success.

Applicant's attention is drawn to In re Dillon, 16 USPQ2d 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

The instant claims are directed to effecting a biochemical pathway with an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for these compounds are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. In the instant invention, the claims are directed to the ultimate neurodegenerative therapy utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D., Ph.D whose telephone number is 571-272-0631. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Russell Travers, J.D, Ph.D.**  
**Primary Examiner**  
**Art Unit 1617**